# LOTRIMIN ULTRA ATHLETES FOOT- butenafine hydrochloride cream Bayer Healthcare LLC.

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Lotrimin Ultra®

Athlete's Foot

**Drug Facts** 

## **Active ingredient**

Butenafine hydrochloride 1%

#### **Purpose**

Antifungal

#### Uses

- cures most athlete's foot between the toes. Effectiveness on the bottom or sides of foot is unknown.
- cures most jock itch and ringworm
- relieves itching, burning, cracking, and scaling which accompany these conditions

#### Warnings

#### For external use only

#### Do not use

- on nails or scalp
- in or near the mouth or the eyes
- for vaginal yeast infections

**When using this product** do not get into the eyes. If eye contact occurs, rinse thoroughly with water.

Stop use and ask a doctor if too much irritation occurs or irritation gets worse

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

## **Directions**

- adults and children 12 years and older:
  - use the tip of the cap to break the seal and open the tube
  - wash the affected skin with soap and water and dry completely before applying
  - **for athlete's foot between the toes**: apply to affected skin between and around the toes twice a day for 1 week (morning and night), or once a day for 4 weeks, or as directed by a doctor. Wear well-fitting, ventilated shoes. Change shoes and socks at least once daily.
  - **for jock itch and ringworm**: apply once a day to affected skin for 2 weeks or as directed by a doctor
  - wash hands after each use
- children under 12 years: ask a doctor

#### Other information

- do not use if seal on tube is broken or not visible
- store between 20° to 25°C (68° to 77°F)

## **Inactive ingredients**

benzyl alcohol, cetyl alcohol, glycerin, glyceryl monostearate SE, polyoxyethylene (23) cetyl ether, propylene glycol dicaprylate, purified water, sodium benzoate, stearic acid, trolamine, white petrolatum Distributed by Bayer HealthCare LLC, Whippany, NJ 07981

## PRINCIPAL DISPLAY PANEL - 12 g Tube Carton

LOTRIMIN ULTRA ®

butenafine hydrochloride cream 1%

ANTIFUNGAL

NET WT 12g (0.42 OZ)



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61-805-21011

Apply between and

81281558

or visit us at www.lotrimin.com Questions? 1-866-360-3226

PRESCRIPTION STRENGTH

Bayer, the Bayer Cross and Lotrimin Ultra are registered trademarks of Bayer. © 2015 Bayer. Dist by: Bayer HealthCare LLC, Whilppany, NJ 07981 Product of Japan.

Bayer

Questions? 1-866-360-3226 or visit us at www.lob

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DUK/NO VARNISH

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- Butenatine hydrochloride 1% lsgnu†ijfu/

Purpose Active ingredient

Drug Facts

PRESCRIPTION STRENGTH

LOTRIMIN UTRY

Contains the Drug: BUTENAFINE HYDROCHLORIDE

#### LOTRIMIN ULTRA ATHLETES FOOT

butenafine hydrochloride cream

#### **Product Information**

**Route of Administration** 

Product Type HUMAN OTC DRUG NDC:11523-4338 Item Code (Source)

**TOPICAL** 

Active Ingredient/Active Moiety

**Basis of Strength Ingredient Name** Strength BUTENAFINE HYDRO CHLO RIDE (UNII: R8 XA2029 ZI) (BUTENAFINE -BUTENAFINE

UNII:91Y494NL0X) HYDROCHLORIDE in 100 g

Inactive Ingredients			
Ingredient Name	Strength		
BENZYL ALCOHOL (UNII: LKG8494WBH)			
CETYL ALCOHOL (UNII: 936JST6JCN)			
GLYCERIN (UNII: PDC6A3C0OX)			
<b>CETETH-23</b> (UNII: 495CTZ441V)			
PROPYLENE GLYCOL DICAPRYLATE (UNII: 581437HWX2)			
WATER (UNII: 059QF0KO0R)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
TROLAMINE (UNII: 903K93S3TK)			
PETROLATUM (UNII: 4T6H12BN9U)			

Product Characteristics					
Color	white (white to off white)	Score			
Shape		Size			
Flavor		Imprint Code			
Contains					

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:11523-4338-1	1 in 1 CARTON	02/22/2002		
1		12 g in 1 TUBE; Type 0: Not a Combination Product			
2	NDC:11523-4338-2	1 in 1 CARTON	02/22/2002		
2		15 g in 1 TUBE; Type 0: Not a Combination Product			
3	NDC:11523-4338-4	1 in 1 CARTON	02/22/2002		
3		30 g in 1 TUBE; Type 0: Not a Combination Product			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
NDA	NDA021307	02/22/2002			

## Labeler - Bayer Healthcare LLC. (112117283)

Revised: 11/2019 Bayer Healthcare LLC.